



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1167]

Ag-Mark, Inc., et al.; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 19 new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from multiple holders of these applications. The basis for the withdrawals is that the holders of these applications have repeatedly failed to file required annual reports for the applications.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The holders of approved applications to market new animal drugs are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 514.80 (21 CFR 514.80).

In the Federal Register of December, 17, 2012 (77 FR 74672), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 19 NADAs and 1 ANADA because the sponsors had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for a hearing as required by § 514.200(b) (21 CFR 514.200(b)) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Veterinary Medicine, is withdrawing approval of the 20 applications listed in Table 1 of this document.

Table 1.--NADAs and ANADA for Which Approval is Withdrawn

Application No.	Trade Name (drug)	Applicant
NADA 009-252	FUMIDIL B (bicyclohexylammonium fumagillin)	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.
NADA 034-601	SYNCHRO-MATE (flurogestone acetate)	G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077.
NADA 039-284	Swisher Super Broiler 300-108 (amprolium, ethopabate, bacitracin zinc, and roxarsone)	Swisher Feed Division, William Davies Co., Inc., P.O. Box 578, Danville, IL 61832.

NADA 040-920	Chick Grower-Developer Fortified (amprolium)	Honeggers and Co., Inc., 201 W. Locust St., Fairbury, IL 61739.
NADA 094-223	Canine Worm Caps (<u>n</u> -butyl chloride)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
NADA 098-429	Medic-Meal-T Premix (tylosin phosphate)	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.
NADA 098-639	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333-2435.
NADA 106-507	TYLAN 10 (tylosin phosphate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
NADA 110-044	PRO-TONE Plus Pak GF T-1 (tylosin phosphate)	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.
NADA 117-688	Dichlorophene and Toluene Capsules	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.
NADA 120-614	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363.
NADA 120-671	Pet-Worm-Caps (dichlorophene and toluene)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
NADA 121-147	Nutra-Mix TYLAN (tylosin phosphate)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
NADA 122-522	TYLAN Sulfa-G (tylosin phosphate and	Custom Feed Blenders Corp., 540 Hawkeye Ave.,

	sulfamethazine)	Fort Dodge, IA 50501.
NADA 124-391	Nutra-Mix TYLAN-Sulfa Premixes (tylosin phosphate and sulfamethazine)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
NADA 127-195	TYLAN 10 (tylosin phosphate)	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137.
NADA 129-415	Custom Ban Wormer 9.6 BANMINTH (pyrantel tartrate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
NADA 130-092	ALFAVET (alfaprostol)	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.
NADA 141-101	PREEMPT (competitive exclusion culture)	Bioscience Division, of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704.
ANADA 200-187	Isoflurane, USP	Marsam Pharmaceuticals, LLC, Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.

The Director, Center for Veterinary Medicine, under section 512(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(2)(A)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 514.80. In addition, under § 514.200(b), we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these applications.

Dated: February 27, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-04998 Filed 03/06/2013 at 8:45 am; Publication Date: 03/07/2013]